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RESEARCH TRIANGLE PARK, NC 27709-3398			ART UNIT	PAPER NUMBER
			3626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/089,708

Applicant(s)

ANDERSON ET AL.

Examiner

NEAL R. SEREBOFF

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date 7/18/2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant/ Response to Amendment

1. In the amendment dated 12/21/2007, the following has occurred: Claims 1 – 78 have been amended. Claims 1 - 78 are pending and the Information Disclosure Statement (PTO-1449) submitted on 7/18/2007 has been considered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The Examiner reviewed system claim 1's amendments with the understanding of MPEP § 2106 (II)C. A quote from the MPEP is included here for convenience.

"The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

- (A) statements of intended use or field of use,
- (B) "adapted to" or "adapted for" clauses,
- (C) "wherein" clauses, or
- (D) "whereby" clauses.

This list of examples is not intended to be exhaustive. See also MPEP § 2111.04."

Claim Rejections - 35 USC § 102

4. ***Claims 1 – 8, 14 – 19, 22 – 28, 32 – 44, 46 – 50, 60, 61, 72 and 73*** are rejected under 35 U.S.C. 102(e) as being anticipated by Martino, U.S. Patent Number 6,044,382.
5. As per claim 1, Martino teaches a system for collecting and providing selective access to medical data relevant to plural patients having related medical conditions comprising:
 - A network computer system (figure 4);

- Associated with the network computer system, a first patient-specific database (column 26, lines 42 – 65) and a second condition-specific database (column 29, lines 27 – 54 where the second database determines the actions performed next if a change is detected);
- Remote from said network computer system, plural patient electronic data collectors, each adapted for collecting first and second patient data relevant to a particular patient's medical condition, said first patient data comprising patient personal data and said second patient data comprising patient data relating to the medical condition of the patient (column 28, lines 42 – 51 where a monitor is set up remotely. The statements following “adapted for” are considered intended use and therefore not given patentable weight);
- Associated with each patient electronic data collector, a communicator for communicating with an entypoint to said network computer system to enable transfer of said first patient data to said first patient-specific database and to enable transfer of said second patient data to said second condition-specific database (column 28, lines 42 – 51 where the connection is performed using a modem. The statements following enabled to are considered the intended use and therefore not given patentable weight);
- A first secure access gateway permitting access to the first patient-specific database in response to a first user authorisation command (column 24, lines 55 – 67 where authorization limits access); and
- A second secure access gateway permitting access to the second condition-specific database in response to a second user authorisation command (column 24, lines 55 – 67 where authorization limits access).

6. As per claim 2, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said patient electronic data collectors are adapted to collect said first and second patient data on a regular basis (column 29, line 55 through column 30, line 9).
7. As per claim 3, Martino teaches the system of claim 2 as described above. Martino further teaches the system wherein said patient electronic data collectors are adapted to collect the first and second patient data on a continuous basis (column 29, line 55 through column 30, line 9).
8. As per claim 4, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said first and second patient data comprises diagnostic data for use in diagnosing each patient's medical condition (column 29, lines 27 – 54 where vital signs are collected).
9. As per claim 5, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said first and second patient data comprises compliance data for use in assessing each patient's compliance with a treatment or prescribing regime (column 29, line 55 through column 30, line 9 where the patient is reminded to perform a function and his vital signs are then monitored and thus determining compliance).
10. As per claim 6, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient has a similar or identical medical condition (column 30, lines 4 – 9 where the patients have similarly critical medical conditions).
11. As per claim 7, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient is on a similar or identical treatment or

prescribing regime (column 28, line 52 through column 29 line 25 where the patient uses the same forms and therefore the same treatments depending upon the forms answers).

12. As per claim 8, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient electronic data collector is under the control of an individual patient (column 28, line 52 through column 29 line 25 where the patient has the monitors at his house).

13. As per claim 14, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the communicator is adapted for communicating wirelessly with the endpoint to the network computer system (column 3, line 66 through column 4, line 21).

14. As per claim 15, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second patient data is communicable between the patient electronic data collector and the network computer system in encrypted form (column 24, line 55 – 67).

15. As per claim 16, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second patient data is continuously communicable between the patient electronic data collector and the network computer system (column 29, line 55 through column 30, line 9).

16. As per claim 17, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second patient data is communicable in packet form between the patient electronic data collector and the network computer system (column 10, lines 52 – 67).

17. As per claim 18, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the network computer system is under the control of a healthcare data manager (column 28, lines 42 – 51 where the doctor controls the system).

18. As per claim 19, Martino teaches the system of claim 18 as described above. Martino further teaches the system wherein the healthcare data manager is associated with a healthcare organisation selected from the group consisting of a doctor's practice, a hospital, a healthcare management centre and a pharmaceutical company (column 28, lines 42 – 51 where the organization is a doctor's practice).

19. As per claim 22, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the data within either database is partitioned according to level of confidentiality or level of commercial sensitivity (column 24, line 54 through column 25, line 4 where the different security levels allow for different levels of database access).

20. As per claim 23, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second secure access gateways are distinct from each other (column 29, lines 55 – 67 where the access is at a patient's home or at a medical kiosk).

21. As per claim 24, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second secure access gateways are coupled or arranged in series (column 32, lines 1 – 16 where the gateways are coupled through the Internet).

22. As per claim 25, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the secure access gateways are password protected (column 28, lines 52 – 67).

23. As per claim 26, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second user authorisation commands are distinct (column 28, lines 52 – 67 where the nurse and the patient have different security levels and the nurse can access more information).

24. As per claim 27, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the first and second user authorisation commands are identical (column 28, lines 52 – 67 where the nurse can access more information than the patient and thus access both patient information and diagnosis information).

25. As per claim 28, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the authorised users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof (column 28, lines 52 – 67 where the nurse is a healthcare professional).

26. As per claim 32, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein information from a remote datasource is made available to the network computer system (figure 11 where all databases are connected through the Internet).

27. As per claim 33, Martino teaches the system of claim 32 as described above. Martino further teaches the system wherein said remote datasource comprises data relating to ambient environmental conditions (column 26, lines 42 – 65 where the ambient conditions are recorded by video and further where the exact information stored within a database is nonfunctional).

28. As per claim 34, Martino teaches the system of claim 32 as described above. Martino further teaches the system wherein the remote datasource comprises a database of prescribable

medicaments (column 19, lines 22 – 40 where the database includes prescription information and further where the exact information stored within a database is nonfunctional).

29. As per claim 35, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the patient electronic data collector further comprises

- A patient electronic data management system comprising a memory for storage of data (column 7, lines 41 – 67 where the computer has memory as shown in column 7, lines 16 – 40);
- A microprocessor for performing operations on said data (column 7, lines 41 – 67); and
- A transmitter for transmitting a signal relating to the data or the outcome of an operation on the data (column 8, lines 29 – 60 where the information is sent to a display).

30. As per claim 37, Martino teaches the system of claim 35 as described above. Martino further teaches the system wherein the communicator adapted for two-way transfer of data between the network computer system and the patient electronic data management system (column 5, lines 39 – 60 where the network is two-way).

31. As per claim 38, Martino teaches the system of claim 1 as described above. Martino further teaches the system additionally comprising

- An authorised user data communicator comprising
 - An authorised user electronic data management system comprising
 - A memory for storage of data (column 7, lines 41 – 67 where the computer has memory as shown in column 7, lines 16 – 40);
 - A microprocessor for performing operations on said data (column 7, lines 41 – 67); and

- A transmitter for transmitting a signal relating to the data or the outcome of an operation on the data (column 8, lines 29 – 60 where the information is sent to a display); and
 - A communicator for communicating with an endpoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system (column 8, lines 29 – 60 where the information is sent to a display).
32. As per claim 39, Martino teaches the system of claim 38 as described above. Martino further teaches the system for the remote assessment of a patient's medical condition and remote prescription therefor comprising
- A first authorised user data communicator capable of communicating a prescription authorisation command to the network computer system (column 26, lines 42 – 65 where the data transaction system transmits a prescription to a pharmacist); and
 - A second authorised user data communicator capable of receiving a prescription authorisation command from the network computer system (column 26, lines 42 – 65 where the pharmacist receives the transmitted prescription).
33. As per claim 40, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein any communicator employs radiofrequency or optical signals (column 38, lines 25 – 29).
34. As per claim 41, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein any communicator is adapted to communicate with the

network computer system via a gateway thereto (column 5, lines 38 – 59 where the devices are networked).

35. As per claim 42, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the communicator includes an embedded network server (column 4, line 66 through column 5, line 13 where the server is part of the network described in column 5, lines 38 – 59).

36. As per claim 43, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the communicator is adapted to communicate with the network computer system via a second communications device having telecommunications capability (column 5, lines 38 – 59 where the network could be cellular).

37. As per claim 44, Martino teaches the system of claim 43 as described above. Martino further teaches the system wherein the telecommunications device comprises a cellular phone or pager (column 32, lines 1 – 16 where the device includes a cellular phone).

38. As per claim 46, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the communicator is adapted to communicate with a specifiable network address of the network computer system (column 5, lines 39 – 60 where 2 or more devices communicate with each other over a network).

39. As per claim 47, Martino teaches the system of claim 46 as described above. Martino further teaches the system wherein the specifiable network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address (column 7, lines 41 – 67 where a web-site address is used to download information).

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40. As per claim 48, Martino teaches the system of claim 35 as described above. Martino further teaches the system wherein the patient electronic data management system additionally comprises a data input system for patient input of data to the electronic data management system (column 8, lines 42 – 65 where patient data is inputted).

41. As per claim 49, Martino teaches the system of claim 48 as described above. Martino further teaches the system wherein said data input system comprises a man machine interface selected from a keypad, graphical user interface (GUI), voice recognition interface or biometrics interface (column 8, lines 42 – 65 where the input system comprises a keyboard).

42. As per claim 50, Martino teaches the system of claim 35 as described above. Martino further teaches the system comprising a display for display of data from the patient electronic data management system to the patient (column 7, lines 41 – 67 where a display is used to present the information).

43. As per claim 60, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the plural patients have related cardiovascular conditions and each patient electronic data collector additionally comprises a sensor adapted for sensing the cardiovascular activity of a patient, wherein the sensor is adapted for communicating cardiovascular data to the patient electronic data collector (column 28, line 52 through column 29, line 25 where the blood pressure monitor connects directly to the system and where the patient type is non-functional descriptive information).

44. As per claim 61, Martino teaches the system of claim 60 as described above. Martino further teaches the system wherein said sensor is adapted for measuring the blood pressure of the patient (column 28, line 52 through column 29, line 25).

45. As per claim 72, Martino teaches the system of claim 1 as described above. Martino further teaches the network computer system comprising

- An interface capable of receiving first and second patient data in electronic form from plural patient electronic data collectors, wherein said first patient data is specific to the patient and said second patient data is specific to the medical condition of the patient (column 28, line 52 through column 29, line 25 where the ports are the interface);
- Associated with said interface, a first patient-specific database (column 26, lines 42 – 65) and a second condition-specific database for storing said first and second patient data database respectively (column 26, lines 42 – 65 where the patient data is stored within the same database); and
- An authorised user inquiry system comprising either or both of
 - (a) A first secure access gateway permitting access to the first patient-specific database in response to a first user authorisation command;
 - First search means for searching said patient-specific database in response to a first authorised user inquiry (column 19, line 1 – 20 where the web interface allows for searching the database); and
 - First results transmitting means for transmitting the results of said first authorised user inquiry to the first authorised user (column 19, line 1 – 20 where the web interface allows for searching the database and where the results are then displayed within the browser);
 - (b) A second secure access gateway permitting access to the second condition-specific database in response to a second user authorisation command;

- Second search means for searching said second condition-specific database in response to a second authorised user inquiry; and
- Second results transmitting means for transmitting the results of said second authorised user inquiry to the second authorised user, wherein the first and second patient data originates remotely from the network computer system.

46. As per claim 73, Martino teaches the network computer system of claim 72 as described above. Martino further teaches the network computer system wherein the network address comprises a web-site address or a file transfer protocol address (column 19, lines 1 – 20 where a web-site address is used).

Claim Rejections - 35 USC § 103

47. ***Claims 9 – 13 and 36*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Abreu, U.S. Pre-Grant Publication Number 2002/ 0049389.

48. As per claim 9, Martino teaches the system of claim 1 as described above. Martino does not explicitly teach the system wherein any patient electronic data collector is integrated with a system for the delivery of medicament.

However, Abreu teaches the system wherein any patient electronic data collector is integrated with a system for the delivery of medicament (paragraph 102).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

49. As per claim 10, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the medicament delivery system is adapted to provide respirable delivery of medicament to the patient.

However, Abreu teaches a system wherein the medicament delivery system is adapted to provide respirable delivery of medicament to the patient (paragraph 1112).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

50. As per claim 11, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the medicament delivery system is adapted to provide injectable delivery of medicament to the patient.

However, Abreu teaches a system wherein the medicament delivery system is adapted to provide injectable delivery of medicament to the patient (paragraph 1112).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

51. As per claim 12, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the medicament delivery system is an implant in the body of the patient.

However, Abreu teaches a system wherein the medicament delivery system is an implant in the body of the patient (paragraph 1112 where the insulin pump is partially implanted).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

52. As per claim 13, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the patient electronic data collector and the system for delivery of medicament are comprised within a handheld device (paragraph 1019 where the device is a wristband).

However, Abreu teaches a system wherein the patient electronic data collector and the system for delivery of medicament are comprised within a handheld device.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

53. As per claim 36, Martino the system of claim 35 as described above.

Martino does not explicitly teach a system wherein said patient electronic data management system additionally comprises a geographic positioning system.

However, Abreu teaches a system wherein said patient electronic data management system additionally comprises a geographic positioning system (paragraph 243).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (Abreu paragraph 199).

54. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382.

55. As per claim 20, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system wherein the first patient-specific database and the second condition-specific database are separate from each other.

It is the Examiner's position that absent evidence of new or unexpected results, it is not inventive in terms of patentability to take one or more databases ($D_1, D_2, D_3, \dots D_N$) which store one or more pieces of information ($I_1, I_2, I_3, \dots I_N$) and add (or subtract) an additional number of databases (X) to store all or part of the same information by allocating the data between the various databases (that is, D_1 and D_{N+1} store I_1 ; D_2 and D_{N+2} store I_2 ; D_3 and D_{N+3} store I_3 ; ... while D_N and D_{N+X} store I_N).

A modification increasing the number of databases (for example, having two databases store information previously stored by just one database) is analogous to making functions, structures, or actions separable. It is the Examiner's position that when the difference between the claimed invention and the prior art is that the prior art does not disclose an element as separable, as a matter of law, it would have been obvious to one having ordinary skill in the art to make the

element separable. *See* MPEP §2144.04 V. C. and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961). It is desirable to allocate the database information to various databases to enhance data management by organizing content, freeing up hard drive space, and speeding up processing speeds because less data has to be searched.

Examiner posits that Applicants have not asserted any new or unexpected results regarding their hardware configuration (and the software running their hardware configuration) of their server system. Absent such new or unexpected results, such modifications either increasing or decreasing the number of databases would have helped maintain benefits from economies of scale in addition to offering excellent data management, fast response, and room for expansion.

Therefore if the claimed database was not directly disclosed, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Martino to include the additional claimed database. Such a modification would have helped maintain benefits from economies of scale in addition to offering excellent data management, fast response, and room for expansion.

56. As per claim 21, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system wherein the first patient-specific database is a sub-database of the second condition-specific database.

It is the Examiner's position that absent evidence of new or unexpected results, it is not inventive in terms of patentability to take one or more databases ($D_1, D_2, D_3, \dots D_N$) which store one or more pieces of information ($I_1, I_2, I_3, \dots I_N$) and add (or subtract) an additional number of databases (X) to store all or part of the same information by allocating the data between the

various databases (that is, D_1 and D_{N+1} store I_1 ; D_2 and D_{N+2} store I_2 ; D_3 and D_{N+3} store I_3 ; ... while D_N and D_{N+x} store I_N).

A modification increasing the number of databases (for example, having two databases store information previously stored by just one database) is analogous to making functions, structures, or actions separable. It is the Examiner's position that when the difference between the claimed invention and the prior art is that the prior art does not disclose an element as separable, as a matter of law, it would have been obvious to one having ordinary skill in the art to make the element separable. *See* MPEP §2144.04 V. C. and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961). It is desirable to allocate the database information to various databases to enhance data management by organizing content, freeing up hard drive space, and speeding up processing speeds because less data has to be searched.

Examiner posits that Applicants have not asserted any new or unexpected results regarding their hardware configuration (and the software running their hardware configuration) of their server system. Absent such new or unexpected results, such modifications either increasing or decreasing the number of databases would have helped maintain benefits from economies of scale in addition to offering excellent data management, fast response, and room for expansion.

Therefore if the claimed database was not directly disclosed, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Martino to include the additional claimed database. Such a modification would have helped maintain benefits from economies of scale in addition to offering excellent data management, fast response, and room for expansion.

57. *Claims 29 and 30* are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Freeman et al, U.S. Patent Number 6,012,035.

58. As per claim 29, Martino teaches the system of claim 1 as described above. Martino does not explicitly teach a system wherein access to either one or both of the databases involves payment of a fee through an electronic payment means.

However, Freeman teaches a system wherein access to either one or both of the databases involves payment of a fee through an electronic payment means (column 5, lines 30 – 41). It would be obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martin with the motivation to provide the monitoring and management of a cooperative health care provision system through a management service (Freeman column 3, lines 35 – 37).

59. As per claim 29, Martino teaches the system of claim 1 as described above. Martino does not explicitly teach a system wherein communication of patient data to either one or both of the databases results in award of an incentive payment through an electronic payment means.

However, Freeman teaches a system wherein communication of patient data to either one or both of the databases results in award of an incentive payment through an electronic payment means (Addendum, Processing and Electronic Payment of “Yes Credit” claims where the JustCare members receive an incentive discount).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martin

with the motivation to provide the monitoring and management of a cooperative health care provision system through a management service (Freeman column 3, lines 35 – 37).

60. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Blaze, U.S. Patent Number 5,721,777.

61. As per claim 31, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system adapted for enabling the patient to define permissions or authorisations at the time of data collection, data transfer, data storage and data access.

However, Blaze teaches a system adapted for enabling the patient to define permissions or authorisations at the time of data collection, data transfer, data storage and data access (column 7, lines 45 – 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to allow emergency access but still permit the patient to control the routine use of his private records (column 7, lines 53 – 57).

62. **Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Menard, U.S. Patent Number 7,138,902.

63. As per claim 45, Martino teaches the system of claim 42 as described above.

Martino does not explicitly teach a system wherein the communicator is adapted to communicate with the second communications device using spread spectrum radiofrequency signals.

However, Menard teaches a system wherein the communicator is adapted to communicate with the second communications device using spread spectrum radiofrequency signals (column 7, lines 14 – 48).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide health care professionals with access to information for remote diagnostic capabilities; to provide notification of acute conditions possibly requiring immediate assistance, transportation to a medical center, or remote treatment action; to provide a location information of mobile persons for caregivers; to notify responsible parties of the occurrence of a medical condition; and to provide remote intervention assistance by caregivers through verbal or visual interaction (Menard, column 2, lines 14 – 21).

64. **Claims 51 – 59 and 78** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Burton, U.S. Patent Number 6,349,724.

65. As per claim 51, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach a system wherein the plural patients have related respiratory conditions and each patient electronic data collector additionally comprises a sensor adapted for sensing the breath of a user, wherein the sensor is adapted to communicate breath data to the patient electronic data collector.

However, Burton teaches a system wherein the plural patients have related respiratory conditions and each patient electronic data collector additionally comprises a sensor adapted for sensing the breath of a user, wherein the sensor is adapted to communicate breath data to the patient electronic data collector (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

66. As per claim 52, Martino in view of Burton teaches the system of claim 51 as described above.

Martino does not explicitly teach the system wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient.

However, Burton teaches the system wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient (column 8, lines 1 – 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

67. As per claim 53, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

However, Burton teaches the system wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller (column 3, lines 52 – 63 where the exhaled breadth creates the low pressure that then changes the impeller movement).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

68. As per claim 54, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

However, Burton teaches the system wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user (column 5, lines 49 – 64 where the valve senses the pressure from inhaling and exhaling).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

69. As per claim 55, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein said the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

However, Burton teaches the system wherein said the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user (column 5, lines 49 – 64 where the valve senses the pressure from inhaling and exhaling).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

70. As per claim 56, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user.

However, Burton teaches the system wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user (column 8, lines 27 – 45 where the temperature is taken from the air flow).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

71. As per claim 57, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user.

However, Burton teaches the system wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user (column 3, line 64 through column 4, line 7 where the humidity sensor maintains the moisture in conjunction with the patients breath).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

72. As per claim 58, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user.

However, Burton teaches the system wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user (column 8, lines 27 – 44 where the system has an oxygen sensor).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

73. As per claim 59, Martino in view of Burton teaches the system of claim 51 as described above.

Martino does not explicitly teach the system wherein said breath data includes breath cycle data.

However, Burton teaches the system wherein said breath data includes breath cycle data (column 8, lines 27 – 44 where the breathing rate, breathing volume, and breathing time).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

74. As per claim 78, Martino in view of Burton teaches the system of claim 51 as described above.

Martino does not explicitly teach the system wherein said breath data includes peak flow data. However, Burton teaches the system wherein said breath data includes peak flow data (column 8, lines 27 – 44 where the breathing rate, breathing volume, and breathing time provide maximum and minimum breathing rates).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (Burton column 2, lines 26 – 27).

75. ***Claims 62 – 68 and 74 – 77*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Official Notice.

76. As per claim 62, Martino teaches a method for collecting and providing selective user access to medical data relevant to plural patients having related medical conditions comprising

- Locally collecting first and second patient data relevant to each patient's medical condition in electronic form, said first patient data comprising patient personal data and said second patient data comprising patient data relating to the medical condition of the patient (column 28, lines 42 – 52 where the system is set up within a doctor's office);
- Communicating with an entry-point to a network computer system to enable transfer of said patient data to a first patient-specific database and to a second condition-specific

database of said network computer system (column 7, lines 41 – 67 where the entry-point and the databases are connected by the Internet which allows for data communication); and

- Permitting first authorised user access to the first patient-specific database via a first secure access gateway (column 24, lines 55 – 67 where authorization limits access), and/or permitting second authorised user access to the second condition-specific database via a second secure access gateway.

The Examiner takes Official Notice that the position that the arrangement of data within a database is a matter of design choice and therefore not patentable. Second, making databases separable or integral does not affect the database performance and therefore does not change the method. Third, the choice of using two databases over one database could be considered the substitution of one part of another to perform the same task.

The Examiner, after careful review, notes that the fields within the databases are not modified or interpreted or in any way adjusted. The fields are information that is stored and moved but the method does not depend upon a particular data type. Therefore the Examiner takes Official Notice that the data is considered non-functional descriptive information and has no patentable weight. Lastly, one of ordinary skill in the art at the time of the invention could create databases with many types of information as evidenced by Iliff, U.S. Patent Number 5,935,060 (column 3, lines 50 – 65; column 5, lines 43 – 50; column 6, lines 11 – 19)

77. As per claim 63, Martino teaches the method of 62 as described above. Martino further teaches the method comprising collecting the first and second patient data on a regular basis (column 29, line 55 through column 30, line 9).

78. As per claim 64, Martino teaches the method of 62 as described above. Martino further teaches the method comprising collecting the first and second data on a continuous basis (column 29, line 55 through column 30, line 9).

79. As per claim 65, Martino teaches the method of 62 as described above. Martino further teaches the method comprising communicating the first and second patient data in encrypted form (column 24, line 55 – 67).

80. As per claim 66, Martino teaches the method of 62 as described above. Martino further teaches the method wherein the first and second patient data is continuously communicable (column 29, line 55 through column 30, line 9).

81. As per claim 67, Martino teaches the method of 62 as described above. Martino further teaches the method wherein the first and second patient data is communicable in packet form (column 10, lines 52 – 67).

82. As per claim 68, Martino teaches the method of 62 as described above. Martino further teaches the method comprising permitting different levels of access to the first and second patient data to different authorised users (column 24, line 54 through column 25, line 4 where the different security levels allow for different levels of database access).

83. As per claim 74, Martino teaches a method for collecting and providing selective user access to medical data relevant to plural patients having related medical conditions, the method comprising

- Receiving first and second data relevant to each patient's medical condition collected automatically at a plurality of locations, said first patient data comprising patient personal

data and said second patient data comprising patient data relating to the medical condition of the patient (column 28, lines 42 – 51 where a monitor is set up remotely);

- Storing some or all of the received first patient data in a first, patient-specific database (column 5, lines 1 – 14 where the data stored within the relevant database);
- Storing some or all of the received second patient data in a second, condition-specific database (column 5, lines 1 – 14 where the data stored within the relevant database);
- Allowing access to said first database in response to a first user authorisation command (column 24, lines 55 – 67 where authorization limits access); and
- Allowing access to said second database in response to a second user authorisation command (column 24, lines 55 – 67 where authorization limits access).

The Examiner takes Official Notice that the position that the arrangement of data within a database is a matter of design choice and therefore not patentable. Second, making databases separable or integral does not affect the database performance and therefore does not change the method. Third, the choice of using two databases over one database could be considered the substitution of one part of another to perform the same task.

The Examiner, after careful review, notes that the fields within the databases are not modified or interpreted or in any way adjusted. The fields are information that is stored and moved but the method does not depend upon a particular data type. Therefore the Examiner takes Official Notice that the data is considered non-functional descriptive information and has no patentable weight.

84. As per claim 75, Martino teaches the method of claim 74 as described above. Martino further teaches the method wherein the first and second patient data is received and access to the

databases is allowed via a network using TCP/IP (column 7, lines 41 – 67 where the information is sent via the Internet and as shown in Reference U, the Internet is a global network of computer networks based on the TCP/IP protocol.).

85. As per claim 76, Martino teaches the method of claim 74 as described above. Martino further teaches the method comprising program means for, when executed on a computer, instructing the computer to perform all of the steps (column 17, lines 33 – 54).

86. As per claim 77, Martino teaches a computer program product comprising

- A computer readable recording medium having recorded thereon a computer program comprising
 - Code means for, when executed on a computer, instructing said computer to perform the steps (column 17, lines 33 – 54) of
 - Receiving first and second patient data relevant to each patient's medical condition collected automatically at a plurality of locations, said first patient data comprising patient personal data and said second patient data comprising patient data relating to the medical condition of the patient (column 28, lines 42 – 51 where a monitor is set up remotely);
 - Storing some or all of the received data in a first, patient-specific database (column 5, lines 1 – 14 where the data stored within the relevant database);
 - Storing some or all of the received data in a second, condition-specific database (column 5, lines 1 – 14 where the data stored within the relevant database);

- Allowing access to said first database in response to a first user authorisation command (column 24, lines 55 – 67 where authorization limits access); and
- Allowing access to said second database in response to a second user authorisation command (column 24, lines 55 – 67 where authorization limits access).

The Examiner takes Official Notice that the position that the arrangement of data within a database is a matter of design choice and therefore not patentable. Second, making databases separable or integral does not affect the database performance and therefore does not change the method. Third, the choice of using two databases over one database could be considered the substitution of one part of another to perform the same task.

The Examiner, after careful review, notes that the fields within the databases are not modified or interpreted or in any way adjusted. The fields are information that is stored and moved but the method does not depend upon a particular data type. Therefore the Examiner takes Official Notice that the data is considered non-functional descriptive information and has no patentable weight. Lastly, one of ordinary skill in the art at the time of the invention could create databases with many types of information as evidenced by Iliff, U.S. Patent Number 5,935,060 (column 3, lines 50 – 65; column 5, lines 43 – 50; column 6, lines 11 – 19)

87. *Claims 69 – 71* are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Freeman et al, U.S. Patent Number 6,012,035.

88. As per claim 69, Martino teaches the method of 62 as described above.

Martino further teaches the method comprising

- A first authorised user communicating a prescription authorisation command to the network computer system (column 26, lines 42 – 65 where the data transaction system transmits a prescription to a pharmacist);
- A second authorised user receiving said prescription authorisation command from the network computer system (column 26, lines 42 – 65 where the pharmacist receives the transmitted prescription).

Martino does not explicitly teach said second authorised user preparing the prescription based on the prescription authorisation.

However, Freeman teaches said second authorised user preparing the prescription based on the prescription authorisation (column 8, lines 37 – 43 where the prescription is filled).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martin with the motivation to provide the monitoring and management of a cooperative health care provision system through a management service (Freeman column 3, lines 35 – 37).

89. As per claim 70, Martino teaches the method of 62 as described above. Martino further teaches the method comprising

- A first authorised user communicating a prescription authorisation command to a pharmacy network computer system (column 26, lines 42 – 65 where the data transaction system transmits a prescription to a pharmacist);
- A second authorised user receiving said prescription authorisation command from the pharmacy network computer system (column 26, lines 42 – 65 where the pharmacist receives the transmitted prescription).

Martino does not explicitly teach said second authorised user preparing the prescription for the patient based on the prescription authorisation, wherein the pharmacy network computer system is arranged for communication with the network computer system.

However, Freeman teaches said second authorised user preparing the prescription for the patient based on the prescription authorisation, wherein the pharmacy network computer system is arranged for communication with the network computer system (column 8, lines 37 – 43 where the prescription is filled based upon the notification sent through the connected network).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martin with the motivation to provide the monitoring and management of a cooperative health care provision system through a management service (Freeman column 3, lines 35 – 37).

90. As per claim 71, Martino in vie of Freeman teaches the method of 69 as described above. Martino further teaches the method wherein the first authorised user communicates the prescription authorisation in response to a 'update prescription' alerting signal visible at a patient-specific network address on the network computer system (column 29, lines 27 - 54 where the change of patient status creates an alarm requiring different medication).

Response to Arguments

91. Applicant's arguments, see claim objections, filed 12/21/2007, with respect to claim 72 have been fully considered and are persuasive. The objection of claim 72 has been withdrawn.

92. Applicant's arguments filed 12/21/2007 have been fully considered but they are not persuasive. Although the arguments are based upon the amended claims, the Examiner is responding to them here to best guide the Applicant on potential future amendments.

- Independent Claim 1, System claim
 - The Applicant's arguments center on whether the "separate databases" storing various information is patentable. The question the Examiner makes when reviewing the claims is whether the database design creates a specific functionality that differentiates it from other database designs. For example, why limit the databases into two databases when some number n, when n is between 3 and 100, would work? MPEP 2105 "If the prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim."
 - As mentioned above, the Applicant has added language that is focused upon two parts discussed in MPEP 2106(C). The first is language describes the intended use of the claim; "adapted for collecting," "enable transfer of." The second is language suggesting that a feature is optional such as "wherein."
 - The Examiner notes that changing the "data" to "first and second data" does not add anything more than adding labels to the data as much as calling it 'good data' or 'bad data.' These labels are not patentable.
 - In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., different secure access gateways) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- Independent claims 62 and 74, method claims

- The Applicant has added statements to the claims to distinguish the data from the prior art. MPEP 2106.01 discusses two types of data, functional descriptive material and nonfunctional descriptive material. “‘Nonfunctional descriptive material’ includes but is not limited to music, literary works, and a compilation or mere arrangement of data. The Applicant’s inclusion of “first and second” data is considered the compilation of data.
- The Examiner has used sections from MPEP 2144 within the newly amended method claims. The Applicant should review these sections further as they best describe the change of database structures (combination or making separable) or the movement of databases or data within databases (arrangement of parts).

93. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

94. The Examiner has reviewed the Applicant's specification. The Examiner has found several references that relate to the disclosed subject matter. The Examiner suggests that the Applicant carefully review all the cited references in light of recent US Supreme Court decisions before making future amendments.

Conclusion

95. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

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/N. R. S./
Examiner, Art Unit 3626
2/7/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626